NICE National Institute for Health and Care Excellence

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Sent via email

[redacted]
KCUK Trustee
Kidney Cancer UK

23 April 2013

Dear [redacted]

Final Appraisal Determination: axitinib for the treatment of advanced renal cell carcinoma after failure of prior systemic treatment

Thank you for lodging Kidney Cancer UK's appeal against the above Final Appraisal Determination.

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

I can confirm that there will be an oral hearing of the appeal.

Initial View

Ground 1

1.1. Difference of views and failure to invite Professor Hawkins to the second appraisal meeting.

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I am not presently minded to regard this as a valid appeal point for the following reasons. The committee's procedural obligation is to conduct a fair appraisal process. That does require the main issues in an appraisal to be identified, and an explanation of the Committee's provisional views given, so as to allow for intelligent response. That seems to have happened here, and intelligent responses were made.

Fairness also requires that response is taken into account when preparing the output of the appraisal process, although whether or not it is persuasive is a question of justification (ground 2) rather than fairness.

Past appeal committees have commented on the degree of reasoning required in a FAD, which is not a consultation document. They have commented that a FAD must be sufficiently reasoned to take effect as guidance (in other words, the informed reader must be able to understand what the reasons for the conclusion are, so he or she can take those conclusions into account when exercising clinical judgment). That is a different purpose to being sufficiently reasoned to enable readers to understand why an experts view did not persuade in the final analysis. At present I do not think the obligation of fairness extends that far.

I am unclear what more a committee would reasonably be required to do. It seems to me that what remains is a disagreement between experts. Each can explain the reasons for their views, but to what extent is it possible to give reasons as to why one view is preferred over another?

I am not minded to refer this point as valid, but will wait for your comments.

As to attendance at the second committee meeting, an appeal committee considered a similar point in the appeal in the guidance for Ranibizumab for the treatment of diabetic macular oedema TA 237. While appeal committees do not set precedents I am guided by their past decisions as I expect them to be broadly consistent. I am not minded to refer this point on as valid, in light of the approach taken in TA 237, but invite your comment on that approach before taking a final decision.

1.2 Uncertainty concerning OS and ICERS

I have doubts about this appeal point precisely as put, which seems to me to be something of a disagreement on the evidence, which might be a ground two appeal point, but would not be a ground one appeal point. However other appellants are appealing on grounds connected with uncertainty around the ICERs which are more focused on procedural issues. Under the circumstances I think it is most helpful to consider this point valid, so that you can attend the hearing and participate in the discussion around that issue, but with a caveat that the hearing may not adhere precisely to the point you have raised.

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As I agree some of your appeal points are valid they will be passed to an appeal panel for consideration. There will be an oral hearing. I would be grateful to receive your comments on the point I am presently not minded to treat as valid within 10 working days of this letter, no later than **Wednesday 8 May,** whereupon I will take a final decision.

Yours sincerely

[redacted]
Appeals Committee Chair
National Institute for Health and Care Excellence